

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

TRUTEK CORP.,

Case No. 4:21-cv-10312

Plaintiff,

Hon. F. Kay Behm

v.

BLUEWILLOW BIOLOGICS, INC.,
et. al.

Defendants.

**PLAINTIFF TRUTEK CORPORATION'S BRIEF IN REPLY TO
DEFENDANT BLUEWILLOW BIOLOGICS, INC.'S OPPOSITION TO
MOTION TO EXCLUDE TESTIMONY OF MANSOOR M. AMIJI PH.D.**

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I. PROCEDURAL HISTORY

Pursuant to E.D. Mich. L.R. 7.1(a), on January 17, 2023, a conference was held between attorneys for Plaintiff, Trutek Corp. ("Trutek") and Defendant, BlueWillow Biologics, Inc. ("BlueWillow"). At that conference, regarding Plaintiff's motion to exclude the testimony of Defendant's expert, Mansoor M. Amiji, Ph.D, ("Amiji" or "Dr. Amiji"), the movant explained the nature of the motion and its legal basis and requested but did not obtain concurrence in the relief sought.

II. INTRODUCTION

The issues presented in this motion are simple:

1. Questions of law are resolved by the court, while questions of fact are resolved by the trier of fact, which in this Present Matter is a jury.¹

2. Plaintiff does not challenge the qualifications of Dr. Amiji as an expert in pharmaceutical science. However, Amiji admits that he is not an attorney and that counsel informed him of the relevant law regarding patent invalidity. Many of Amiji's opinions are legal in nature quoting case laws and statutes. Yet, Amiji does not show that he has an understanding of the law. He is also unaware of the standards and procedures of the United States Patent and Trademark Office ("USPTO") regarding patents. Amiji also admits that he did not perform his own research into

¹ *State of Georgia v. Brailsford*, 3 U.S. 1, 4 (1794); *Sparf v. U.S.*, 156 U.S. 51, 64 (1895); *Merck Sharp & Dohme v. Albrecht*, 139 S.Ct. 1668, 1680 (2019)

the relevant patent prior art, but that counsel supplied him with copies of said prior art. (*Depo. Amiji*, 60:8-15.)

3. Many of Dr. Amiji's opinions are based on interpretations of patent law that are incorrect. Any testimony by him that interprets facts based on incorrect law would confuse the jury.

4. Many of Dr. Amiji's opinions require interpretation from the viewpoint of a person having ordinary skill in the art ("POSA"). But, Dr. Amiji is a person with *extraordinary skill in the art*. In his deposition and expert reports, Dr. Amiji opined on qualifications necessary for a POSA. When asked, he viewed himself as a POSA. Dr. Amiji's proposed qualifications for a POSA were rejected by this court. Thus, all opinions requiring the viewpoint of a POSA are made through the wrong lens.

III. THE OPINIONS PUT FORTH BY AMIJI

A. The Person of Ordinary Skill in the Art

On Page 28 of his opening report on invalidity (ECF 73-1), Dr. Amiji wrote:

I came to the conclusion that the characteristics of a person of ordinary skill in the art of the '802 Patent would be someone who had at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation. Also, a person of ordinary skill in the art may have worked as part of a multidisciplinary team—including a chemical engineer, microbiologist, or polymer chemist—and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team, e.g., to solve a given problem.

Dr. Amiji's Deposition is submitted herewith as Exhibit 1. On Page 81, he was asked the question, "Okay. Do you consider yourself a person of ordinary skill or somebody with extraordinary skill?" To which he answered:

Based on my definition of a person of ordinary skill in the art, and based on the priority date of this patent, I would consider myself a person of ordinary skill in the art.
(*Id.* at Page 82.)

Amiji's opinion of the qualifications of a POSA was rejected by this Court (ECF 53, Pages 8-10). The Court stated:

In sum, because Amiji failed to adequately support his claim that an advanced degree was required, the Court will adopt Plaintiff's definition of a "person of ordinary skill in the art" of pharmaceutical formulation. (Id. at Page 10.)

This is critical because Dr. Amiji forms all of his opinions from his own viewpoint rather than the viewpoint of a person of ordinary skill. What may be obvious to one of Dr. Amiji's education, skill, and experience may not be so to a person with fewer qualifications. Dr. Amiji does not appear to be able to see things from the viewpoint of an actual POSA.

B. Summary of Dr. Amiji's Opinions

In Dr. Amiji's opening report on patent invalidity, he presents the following opinions:

IX. ANALYSIS: CLAIMS 1, 2, 6, AND 7 ARE INVALID IN VIEW OF WADSTROM ALONE, OR IN COMBINATION WITH ROLF.
(Page 44.)

- X. ANALYSIS: CLAIMS 1, 2, 6, AND 7 ARE INVALID IN VIEW OF Wahi '488 ALONE, OR IN COMBINATION WITH ROLF.
(Page 58.)
- XI. ANALYSIS: CLAIMS 1, 2, 6, AND 7 ARE INVALID IN VIEW OF BAKER '189 OR BAKER '476 ALONE, OR IN COMBINATION WITH ROLF OR KHALED OR RABE OR KATZ OR WAHI '790.
(Page 74.)

SUBJECT MATTER ELIGIBILITY

- XII. ANALYSIS: CLAIMS 1, 2, 6, AND 7 ARE INVALID FOR BEING DIRECTED TO INELIGIBLE SUBJECT MATTER UNDER 35 U.S.C. § 101. (Page 95.)

CREDIBLE UTILITY, WRITTEN DESCRIPTION, AND ENABLEMENT

- XIII. ANALYSIS: CLAIMS 1, 2, 6, AND 7 ARE INVALID FOR LACK OF CREDIBLE UTILITY. (Page 99.)
- XIV. ANALYSIS: CLAIMS 1, 2, 6, AND 7 ARE INVALID FOR LACK OF ENABLEMENT. (Page 101.)
- XV. ANALYSIS: CLAIMS 1, 2, 6, AND 7 ARE INVALID FOR LACK OF ADEQUATE WRITTEN DESCRIPTION. (Page 108.)

On Page 13 of its brief in opposition to Defendant's motion to exclude Dr. Amiji's testimony, Defendant states, "[s]ix of these statements are merely section titles, a convenient road map to aid anyone reading the report." Contrast this statement with one following immediately on Page 14.

Each of these eight opinions on patent invalidity are supported throughout the remainder of the report with relevant facts, and the application of reliable methods to those facts.

Here, Defendant admits that the eight statements *supra* are opinions, and not just section headings. Amiji states his opinions, and then purports to provide the basis for each of those opinions.

IV. AMIJI'S OPINIONS OF INVALIDITY BASED ON PRIOR ART

The opinions labeled X, XI, and XII *supra* represent Amiji's allegations of invalidity of the asserted claims of Plaintiff's '802 Patent based on prior art under 35 U.S.C. §§ 102 and 103.

In my opinion, claims 1, 2, 6 and 7 of the '802 Patent are invalid as anticipated and/or are obvious in view of the prior art described herein under 35 U.S.C. §§ 102 and 103.
(ECF 73-1 at Page 22, ¶ 53.)

In Opinion X, Amiji stated that the asserted claims of the '802 Patent are invalid in view of Wadstrom alone; in Opinion XI ... in view of Wahi '488 alone; in Opinion XII ... in view of Baker '189 or Baker '476 alone. Any of these invalidity assertions must have been based on anticipation under 35 U.S.C. § 102. However, Amiji did not even allege that the prior art references taught all of the elements of the asserted claims.

On pages 53-58 of his deposition (Exhibit 1), Dr. Amiji demonstrates his misunderstanding of the differences between anticipation under 35 U.S.C. § 102 and obviousness under 35 U.S.C. § 103. Further, his determination of obviousness of the asserted claims based on a combination of prior art references is flawed because he is viewing the motivation to combine from the viewpoint of the wrong POSA (*i.e.*, his own viewpoint or at least the viewpoint of someone having an advanced degree and much more experience). In its brief, Defendant asserts that, "Dr. Amiji is qualified to provide testimony from the perspective of a POSA." (ECF 73, Page

6.) While it is true that a person of extraordinary skill in the art is generally qualified to testify as to what a person of ordinary skill would surmise, it is required that the witness understand who is the hypothetical POSA. Unfortunately, Dr. Amiji lacks that understanding (argued *supra*).

V. AMIJI'S OPINIONS BASED ON 35 U.S.C. § 101.

In his opinions, Dr. Amiji shows that he lacks a fundamental understanding of patent subject matter eligibility under 35 U.S.C. § 101. Ignoring the four statutory categories of patentable subject matter (*i.e.*, process, machine, manufacture, and composition of matter), he alleges that the claims are invalid because they are "directed" to an abstract concept (*i.e.*, electrostatics, which is a law of nature). He fails to understand that all patentable inventions involve laws of nature. He stated:

My understanding is that for subject matter to be patentable, there has to be some novelty beyond what is well known to personal skill in the art [sic.] as occurring by nature.
(*Depo.* Amiji (Exhibit 1) at 38:9-12.)

First, 35 U.S.C. § 101 does not require the knowledge of a POSA. Also, Amiji does not appear to understand that the asserted claims do not claim electrostatic attraction itself. He does not appear to understand that the Preamble and Element (a) merely utilizes electrostatic attraction. *Id.* at Pages 37-45. *See also* Haidri Report, ECF 73-2, Pages 39-42.

VI. AMIJI'S OPINIONS BASED ON 35 U.S.C. § 112

Opinions XIV and XV *supra* state that the asserted claims are invalid for lacking enablement and adequate written description, respectively. Here, there are two basic flaws in his understanding of the law. First, he states that his objections are based on the fact that the specification fails to provide experimental test data. Nowhere is this required in patent statutes or in USPTO standards and procedures. In fact patents are routinely granted where the inventions have only been constructively reduced to practice. Second, § 112 requires a viewpoint of a POSA, which Amiji does not adequately provide. Finally, the USPTO Examiner stated that the invention, as described and claimed, is enabled under 35 U.S.C. § 112. (ECF 72-1.)

VII. CONCLUSION

For the reasons stated herein, Plaintiff's Motion to Exclude Testimony of Mansoor M. Amiji, Ph.D. should be granted.

Dated: June 9, 2023

Respectfully submitted,

/s/ Stanley H. Kremen

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CERTIFICATE OF SERVICE

I certify that on June 9, 2023, I served the foregoing document upon all parties/counsel of record by filing copies of same using this Court's CM/ECF System.

A handwritten signature in black ink, appearing to read 'Keith Altman', written over a horizontal line.

Keith Altman, Esq.